DOI:
DOI 10.1080/14767058.2018.1547704.
10.1080/14767058.2018.1547704

Document Version
Peer reviewed version

The Journal of Maternal-Fetal & Neonatal Medicine

ISSN: 1476-7058 (Print) 1476-4954 (Online) Journal homepage: http://www.tandfonline.com/loi/ijmf20

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To cite this article: N. Carlisle, M. Chandiramani, J. Carter & A. H. Shennan (2018): Reply: Evaluation of the quantitative fetal fibronectin test and PAMG-1 test for the prediction of spontaneous preterm birth in patients with signs and symptoms suggestive of preterm labor, The Journal of Maternal-Fetal & Neonatal Medicine, DOI: 10.1080/14767058.2018.1547704

To link to this article: https://doi.org/10.1080/14767058.2018.1547704

THE JOURNAL OF MATERNAL-FETAL & NEONATAL MEDICINE
https://doi.org/10.1080/14767058.2018.1547704

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LETTER TO THE EDITOR

Reply: Evaluation of the quantitative fetal fibronectin test and PAMG-1 test for the prediction of spontaneous preterm birth in patients with signs and symptoms suggestive of preterm labor

Sir,

Ravi et al. boldly state that quantitative fetal fibronectin (fFN) with a cutoff threshold of 200 ng/mL has no clinical advantage, despite having a higher positive predictive value (PPV). The authors assume that a threshold of 200 ng/mL would be used to "rule out" preterm birth and fail to appreciate that the strengths of quantitative fFN use in clinical practice do not rely on arbitrary cutoffs.

Through using the entire range of quantitative fFN, predictive abilities and in turn clinical utility is not limited to a fixed threshold. High levels of quantitative fFN can be used to improve PPV, while low levels can be used to rule out imminent delivery. In clinical practice, ruling out imminent delivery is far more important; clinicians only withhold treatment for women at very low risk, but will treat most women at moderate risk or higher [1].

The absence of a power calculation, a small sample of 72 patient and an event rate of only three women who delivered within 7 d of presenting limits the statistical certainty of their findings. Although the authors acknowledge these shortcomings within the discussion, they state that the "PAMG-1 test is a better predictor of spontaneous delivery" and claim that the "PAMG-1 test was statistically superior". Both statements are misleading.

The authors found that both PAMG-1 and fFN (at 10 and 50 ng/mL) have the same sensitivity (67%). Both have poor sensitivity – one third of women who go on to have a preterm birth would be falsely reassured. However, the wide confidence interval (67%, CI 9.43–99.6) make these statistics (and all of their statistics) almost meaningless; this implies in women with actual preterm birth, over 90% could have a negative test, or the test is near perfect. Bigger studies are needed.

By combining quantitative fFN, cervical length and medical history, we have been able to improve prediction statistics to clinically useful levels in appropriately powered studies [2,3]. These are currently being trialed in clinical practice.

Disclosure statement

AHS is currently performing trials supported financially, paid to institute (Hologic, Biomedica), and donated samples (Partosure) to compare fFN, actim partus and Partosure. He is an advisor to NICE on preterm prediction tests.

NC and MC received financial assistance to cover expenses, paid to institute, to provide an educational talk on preterm birth from Hologic, USA. The other authors did not report any potential conflicts of interest.

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Received 7 June 2018; accepted 9 November 2018